

109TH CONGRESS
1ST SESSION

H. R. 2685

To provide for prescription drugs at reduced prices to Medicare beneficiaries.

IN THE HOUSE OF REPRESENTATIVES

MAY 26, 2005

Mr. LARSON of Connecticut (for himself, Mr. GRIJALVA, and Mr. HINCHEY) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To provide for prescription drugs at reduced prices to
Medicare beneficiaries.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare Prescription
5 Drug Price Negotiation Act”.

1 **SEC. 2. AVAILABILITY OF PRESCRIPTION DRUGS FROM**
2 **PARTICIPATING MANUFACTURERS AT NEGO-**
3 **TIATED PRICES.**

4 (a) IN GENERAL.—Each participating manufacturer
5 of a covered outpatient drug shall make available for pur-
6 chase by any qualified Federal health care provider, by
7 each pharmacy, and by each provider of services, physi-
8 cian, practitioner, and supplier under the medicare pro-
9 gram such covered outpatient drug in the amount de-
10 scribed in subsection (b) at the price described in sub-
11 section (c).

12 (b) DESCRIPTION OF AMOUNT OF DRUGS.—The
13 amount of a covered outpatient drug that a participating
14 manufacturer shall make available for purchase under
15 subsection (a) is the sum of—

16 (1) an amount equal to the aggregate amount
17 of the covered outpatient drug dispensed by phar-
18 macies to Medicare beneficiaries; and

19 (2) an amount equal to the aggregate amount
20 of the covered outpatient drug dispensed through
21 qualified Federal health care providers.

22 (c) DESCRIPTION OF PRICE.—

23 (1) IN GENERAL.—The price at which a partici-
24 pating manufacturer shall make a covered outpatient
25 drug available for purchase under subsection (a) is
26 a price that the Secretary, in conjunction with the

1 Secretary of Defense and the Secretary of Veterans
2 Affairs, negotiate with the manufacturer.

3 (2) PROMOTION OF BREAKTHROUGH DRUGS.—

4 (A) IN GENERAL.—In conducting negotia-
5 tions with participating manufacturers under
6 paragraph (1), the Secretary shall take into ac-
7 count the goal of promoting the development of
8 breakthrough drugs.

9 (B) DEFINITION.—For purposes of this
10 paragraph, a drug is a “breakthrough drug” if
11 the Secretary determines it is a new product
12 that will make a significant and major improve-
13 ment by reducing physical or mental illness, re-
14 ducing mortality, or reducing disability, and
15 that no other product is available to enrollees
16 that achieves similar results for the same condi-
17 tion.

18 (d) ENFORCEMENT.—The United States shall debar
19 a manufacturer of drugs or biologicals that does not com-
20 ply with the provisions of this Act.

21 (e) DISPUTE RESOLUTION MECHANISM.—The Sec-
22 retary shall establish a mechanism (such as an ombuds-
23 man) for the resolution of disputes between Medicare
24 beneficiaries and prescription drug resellers and drug

1 manufacturers in order to protect such beneficiaries and
2 to ensure that—

3 (1) prescription drug resellers are not artificially
4 increasing prices charged to Medicare beneficiaries
5 (above those negotiated under subsection (c)) in
6 places where there is less competition (such as in
7 rural areas); and

8 (2) such resellers are not colluding on prices in
9 areas with more potential significant competition.

10 **SEC. 3. ADMINISTRATION.**

11 The Secretary shall issue such regulations as may be
12 necessary to implement this Act.

13 **SEC. 4. REPORTS TO CONGRESS REGARDING EFFECTIVE-**
14 **NESS OF ACT.**

15 (a) IN GENERAL.—Not later than 2 years after the
16 date of the enactment of this Act, and annually thereafter,
17 the Secretary shall report to the Congress regarding the
18 effectiveness of this Act in—

19 (1) protecting Medicare beneficiaries from dis-
20 criminatory pricing by drug manufacturers, and

21 (2) making prescription drugs available to
22 Medicare beneficiaries at substantially reduced
23 prices.

24 (b) CONSULTATION.—In preparing such reports, the
25 Secretary shall consult with public health experts, affected

1 industries, organizations representing consumers and
2 older Americans, and other interested persons.

3 (c) RECOMMENDATIONS.—The Secretary shall in-
4 clude in such reports any recommendations the Secretary
5 considers appropriate for changes in this Act to further
6 reduce the cost of covered outpatient drugs to Medicare
7 beneficiaries.

8 **SEC. 5. DEFINITIONS.**

9 In this Act:

10 (1) PROVIDER OF SERVICES.—The term “pro-
11 vider of services” has the meaning given that term
12 in section 1861(u) of the Social Security Act (42
13 U.S.C. 1395x(u)).

14 (2) PHYSICIAN.—The term “physician” has the
15 meaning given that term in section 1861(r) of the
16 Social Security Act (42 U.S.C. 1395x(r)).

17 (3) PRACTITIONER.—The term “practitioner”
18 has the meaning given that term in section
19 1842(b)(18)(C) of the Social Security Act (42
20 U.S.C. 1395u(b)(18)(C)).

21 (4) SUPPLIER.—The term “supplier” has the
22 meaning given that term under section 1842(o) of
23 the Social Security Act (42 U.S.C. 1395u(o)).

24 (5) COVERED OUTPATIENT DRUG.—The term
25 “covered outpatient drug” has the meaning given

1 that term in section 1927(k)(2) of the Social Secu-
2 rity Act (42 U.S.C. 1396r–8(k)(2)).

3 (6) DEBAR.—The term “debar” means to ex-
4 clude, pursuant to established administrative proce-
5 dures, from Government contracting and subcon-
6 tracting for a specified period of time commensurate
7 with the seriousness of the failure or offense or the
8 inadequacy of performance.

9 (7) MEDICARE BENEFICIARY.—The term
10 “Medicare beneficiary” means an individual entitled
11 to benefits under part A of title XVIII of the Social
12 Security Act or enrolled under part B of such title,
13 or both.

14 (8) PARTICIPATING MANUFACTURER.—The
15 term “participating manufacturer” means any man-
16 ufacturer of drugs or biologicals that, on or after the
17 date of the enactment of this title, enters into a con-
18 tract or agreement with the United States for the
19 sale or distribution of covered outpatient drugs to
20 the United States.

21 (9) SECRETARY.—The term “Secretary” means
22 the Secretary of Health and Human Services.

1 **SEC. 6. EFFECTIVE DATE.**

2 The Secretary shall implement this Act as expedi-
3 tiously as practicable and in a manner consistent with the
4 obligations of the United States.

5 **SEC. 7. CONFORMING AMENDMENT.**

6 Section 1860D–11 of the Social Security Act (42
7 U.S.C. 1395w–111) is amended by striking subsection (i)
8 (relating to noninterference).

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